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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/004,481	11/01/2001	Julian A. Blair	263742002300	6575
25226	7590	04/27/2004	EXAMINER	
MORRISON & FOERSTER LLP			KRISHNAN, GANAPATHY	
755 PAGE MILL RD			ART UNIT	
PALO ALTO, CA 94304-1018			PAPER NUMBER	
			1623	

DATE MAILED: 04/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/004,481	BLAIR, JULIAN A.	
	Examiner	Art Unit	
	Ganapathy Krishnan	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12,14,15 and 17-20 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-12,14,15 and 17-20 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

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DETAILED ACTION

The amendment filed December 20, 2003 has been received, entered and carefully considered. The following information provided in the amendment affects the instant application:

1. Claims 13 and 16 have been canceled.
2. Claims 1, 2 and 15 have been amended.
3. Example 3 at page 27 has been renumbered Example 2.
4. Remarks/Arguments drawn to objection to specification and rejections under 35 USC 112 second paragraph, double patenting and 35 USC 102.

Claims 1-12, 14, 15 and 17-20 are pending in the case.

The text of those sections of Title 35, U. S. Code not included in this action can be found in a prior Office action.

Specification

The objection to specification has been overcome by amendment.

Claim Rejections - 35 USC § 112

The rejection of claim 13 has been rendered moot by cancellation. The rejection of claim 14 has been overcome in view of applicant's remarks. The rejection of claim 15 has been overcome by amendment.

The following new rejections are made of record.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 6 and 17 recite the term derivative. In the absence of the specific derivatizations to the chemical core claimed or distinct language to describe the structural modifications or the chemical names of the derivatives of this invention, the identity of said derivatives would be difficult to describe and the metes and bounds of the said derivatives applicants regard as the invention cannot be sufficiently determined because they have not been particularly pointed out or distinctly articulated.

Double Patenting

The obviousness-type double patenting rejection of instant claims 3-8 over claims 1-6 of U.S. Patent No. 6,352,722 has been overcome by filing a terminal disclaimer that has been approved. An assignee has not been disclosed for the instant application. If the assignee of the instant application is the same as the assignee for US 6517860, which has been used in the rejection below, then additional double patenting rejections will be made of record.

Claim Rejections - 35 USC § 102

The rejection of claim 1 under 35 USC 102(b) has been overcome by amendment.

The following new rejection is made of record.

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-11 are rejected under 35 U.S.C. 102(e) as being anticipated by Roser et al (US 6,517,860) newly cited.

Roser et al teach a composition comprising a bioactive agent and a hydrophobically derivatized carbohydrate. The structural formula of the hydrophobically derivatized carbohydrate is recited at column 14, lines 15-25, wherein the substituent R includes an ester and can be any chain length from C₂ upwards and can be straight, branched, cyclic or modified and mixtures thereof. This meets the limitations of claim 1. The substituted carbohydrates include trehalose octa-3,3-dimethylbutyrate, trehalose octabutyrate and trehalose octapivalate. This meets the limitations of claims 2 and 3. Roser et al teach a composition comprising trehalose octaisobutyrate and fluticasone and further comprising trehalose octacetate (further comprising a hydrophobically derivatized carbohydrate), which is shown to release the fluticasone from the composition (capable of releasing a substance)(col. 12, Example 8 and col. 13, lines 43-47). The trehalose octacetate is a physiologically acceptable glass containing acetate. The composition is also in a solid dose form (solid matrix). Roser et al teach compositions formulated into a wide variety of dosage forms including tablets, suspensions in liquids, gels or creams, capsules, pessaries, gel/polymer matrices, tablets, microspheres (col. 8, line 48 through col.9, line 3). This meets the limitations of claims 4-7. A wide variety of bioactive agents (therapeutic agents) can

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be used in the composition of Roser that include but not limited to those given in Table 1 (col.6, lines 21-41 and col. 1, line 60 through col. 2, line 50 and examples 5 through 9). This meets the limitations of claims 8-11).

Claims 12, 14, 15 and 17-20 are rejected under 35 U.S.C. 102(e) as being anticipated by Roser et al (US 6,517,860) newly cited.

Roser et al teach a method of making the compositions of their invention that comprises mixing the bioactive agent and the carbohydrate and melting the components to form a homogenous mixture and then quenching the melt (col. 9, lines 10-20 and example 8, col. 12). Roser also teaches another method wherein the bioactive agent and the carbohydrate are dissolved in a solvent (col. 9, lines 21-33; col. 12, example 9). These teachings meet the limitations of claims 12, 14, 15 and 17-20.

Conclusion

Claims 1-12, 14, 15 and 17-20 are rejected.

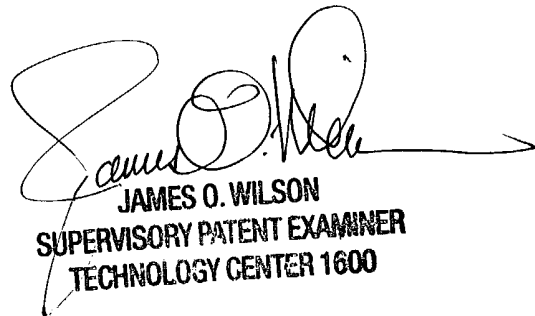
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathy Krishnan whose telephone number is 571-272-0654. The examiner can normally be reached on 8.30am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

GK



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SUPERVISORY PATENT EXAMINER
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